SECTION 2- 510(K) SUMMARY

AUG 17 2007

Name and Address of Applicant
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Contact:
Jack Coggan
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

The QP-156E Exercise Test Option is an optional accessory for the Nihon Kohden ECG-1500A Series or Cardiofax V Electrocardiograph, per 510(k) K052511, commercial distribution certification dated May 24, 2006. The device has been classified as Class II by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 Electrocardiograph as per part 74 DPS.

- **Common or usual Name:** Electrocardiograph/ECG

- **Legally Marketed Predicate:** Nihon Kohden QP-932E ECG Exercise Test Option, 510(k): K972310 commercial distribution certification dated August 20, 1997 for ECG-9320A Cardiofax Electrocardiograph per 510(k) K961272 commercial distribution certification dated November 1, 1996.

Description and Intended Use: The QP-156E Exercise Test Option with its parent device, the Nihon Kohden ECG-1500A Series or Cardiofax V Electrocardiograph, is intended for medical purposes used to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and to prepare a record of the electrical signals produced by the heart. The QP-156E will develop a report based upon acquired data and subsequent calculations. The ECG-1500A Series or Cardiofax V with QP-156E Exercise Test Option will be available for use by a physician within a hospital, laboratory, and clinic or in a remote environment under the supervision of a physician.

A summary of the technological characteristics of the device compared to the predicate device: The QP-156E exercise test software is installed into an ECG-1500A Series or Cardiofax V Electrocardiograph, it can manage exercise testing, perform auto recording and automatically measure heart rate and ST level. After exercise testing, QP-156E can also print a final report and save the examination data in the memory, or in an optional memory card or diskette, or transfer it to other external instruments.
The product is similar to Nihon Kohden predicate device QP-932E Exercise Test Option and it provides setting items and protocol settings that can be changed in the system setting screen. You can use an ergometer and treadmill for exercise stress testing. See attachment # 5 for comparison of the QP-156E and QP-932E Exercise Test Options.

Performance Testing

- The device is not sterile.

- The device was subject to environmental testing including vibration, impact and drop test. EMC testing, including EMI, electrostatic, emission immunity, burst, conductive immunity, voltage dip, commercial frequency magnetic field and attachment document. Safety testing, including labeling, temperature rise, power input, protection against defibrillation discharge, electrical separation, ground resistance, humidity, withstanding voltage, leakage current, deflection, sharp edge, power interruption, creepage distance and air clearance were conducted. See Attachment 8.

There are no significant changes in function, performance or manufacturability compared to the predicate device that would affect the safety and effectiveness of the device as intended for use. Therefore, Nihon Kohden believes that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Nihon Kohden America, Inc.
c/o Mr. Jack Coggan
Regulatory Affairs Director
90 Icon Street
Foothill Ranch, CA 92610

Re: K072060
QP-156E Exercise Test Software
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: Undated
Received: July 27, 2007

Dear Mr. Coggan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement:

510(K) Number (if known): K072060

Device Name: QP-156E Exercise Test Software

Indications for Use:

The QP-156E Exercise Test Option with its parent device, the Nihon Kohden ECG-1500A Series/Cardiofax V Electrocardiograph, is intended for medical purposes used to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and to prepare a record of the electrical signals produced by the heart. The QP-156E will develop a report based upon acquired data and subsequent calculations.

The ECG-1500A Series/Cardiofax V Electrocardiograph with QP-156E Exercise Test Option will be available for use by a physician within a hospital, laboratory, clinic or in a remote environment under the supervision of a physician.

Prescription Use ___X_____ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

B Cummins

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072060

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)